NOV 2 0 2009

K093488

510(k) Summary of Safety and Effectiveness
Prepared in accordance with 21 CFR Part 807.92

Section a):

1. Submitter: Aloka Co., Ltd., 10 Fairfield Boulevard, Wallingford, CT 06492

   Contact Person: Richard J. Cehovsky, RA/QA Mngr.,
   Tel: (203)269-5088 Ext. 346, Fax: 203-269-6075

   Date Prepared: 10/12/09

2. Device Name: Aloka Prosound Alpha 6 Diagnostic Ultrasound System
   Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550 , 90 IYN
   Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90 ITX
   Ultrasonic Pulsed Echo Imaging System., 21 CFR 892.1560, 90 IYO

3. Marketed Device: Aloka SSD-4000 Diagnostic Ultrasound System K040719, (90-IYN, ITX, IYO)
   (A device currently in commercial distribution)

4. Device Description: The Prosound Alpha 6 Diagnostic Ultrasound System is a full feature imaging and analysis system. It consist of a mobile console that provides acquisition, processing and display capability. The user interface includes a computer type keyboard, specialized controls and a display.

5. Indications for Use: The device is intended for use by a qualified physician for ultrasound evaluation of Small Parts, Abdominal, Cardiac, Peripheral Vascular, Fetal, Intra-operative, Trans-vaginal , Trans-rectal, Gynecological and Neonatal Cephalic applications.
   The device is not indicated for Ophthalmic applications.

6. Comparison w/ Predicate Device:
   The Aloka Prosound Alpha 6 is technically comparable and substantially equivalent to the current Aloka SSD-4000-(K040719). It has the same technological characteristics, key safety and effectiveness features, and has the same intended uses and basic operating modes as the predicate device.

Section b):

1. Non-clinical Tests: The device and its transducers have been evaluated for acoustic output, biocompatibility, cleaning & disinfection effectiveness, electromagnetic compatibility, as well as electrical and mechanical safety, and have been found to conform with applicable medical device safety standards.

2. Clinical Tests: None Required.

3. Conclusion: Intended uses and other key features are consistent with traditional clinical practices, FDA guidelines and established methods of patient examination. The design, development and quality process of the manufacturer confirms with 21 CFR 820, ISO 9001:2000 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effectiveness performance. Therefore, it is the opinion of Aloka Co., Ltd. that the Aloka Prosound Alpha 6 Diagnostic Ultrasound System and its transducers are substantially equivalent with respect to safety and effectiveness to its predicate and other currently cleared Aloka systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

FEB 22 2010

Aloka Co., Ltd.
% Mr. Tamas Borsai
Division Manager, Medical Division
TÜV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K093488
Trade/Device Name: Aloka Prosound Alpha 6 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: November 10, 2009
Received: November 10, 2009

Dear Mr. Borsai:

This letter corrects our substantially equivalent letter of November 20, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Aloka Prosound Alpha 6 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

UST-676P
ASU-1010
UST-2266-5
UST-5293/5293S-5
UST-5299
UST-5413

UST-9123
UST-9124
UST-9127
UST-9133

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form
UST-676P
(K023996)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (s
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P	P	P					See Below	Note
Transvaginal		P	P	P					See Below	Note
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD, Note 1: Mflow, B/Bflow, Power flow).

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093488

Diagnostic Ultrasound Indications for Use Form
ASU-1010
(K043196)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal		P	P	P					See Below	Note 1
Abdominal		P	P	P					See Below	Note 1
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other: Gynecological		P	P	P					See Below	Note 1

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD, Note 1: Mflow, B/Bflow, Power flow).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K093488

Diagnostic Ultrasound Indications for Use Form
UST-2266-5
(K020668)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac					P					
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular					P					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K093488

Diagnostic Ultrasound Indications for Use Form
UST-5293/5293S-5
(K003739)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P				See Below	Note 1
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD, B/CWD, B/CD/CWD, Note 1: Mflow, B/Bflow, Power flow).

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093488

Diagnostic Ultrasound Indications for Use Form
UST-5299
(K003739)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P				See Below	Note 1
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M,B/PWD, M/CD, B/CD/PWD, B/CWD, B/CD/CWD, Note 1: Mflow, B/Bflow, Power flow).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K093488

Diagnostic Ultrasound Indications for Use Form
UST-5413
(K992663)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		P	P	P					See Below	Note 1
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P					See Below	Note 1
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD, Note 1: Mflow, B/Bflow, Power flow).

Applications: Small Parts: (breast, testes, thyroid...)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K093488

Diagnostic Ultrasound Indications for Use Form
UST-9123
(K003739)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal		P	P	P					See Below	Note 1
Abdominal		P	P	P					See Below	Note 1
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other: Gynecological		P	P	P					See Below	Note 1

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes- B/M, B/PWD, M/CD, B/CD/PWD, Note 1: Mflow, B/Bflow, Power flow).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093488

Diagnostic Ultrasound Indications for Use Form
UST-9124
(K003739)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal		P	P	P					See Below	Note 1
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal		P	P	P					See Below	Note 1
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other: Gynecological		P	P	P					See Below	Note 1

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD, Note 1: Mflow, B/Bflow, Power flow).

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093488

Diagnostic Ultrasound Indications for Use Form
UST-9127
(K060059)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal		P	P	P					See Below	Note 1
Abdominal		P	P	P					See Below	Note 1
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other: Gynecological		P	P	P					See Below	Note 1

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD, Note 1: Mflow, B/Bflow, Power flow).

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093488

Diagnostic Ultrasound Indications for Use Form
UST-9133
(K060059)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		P	P	P					See Below	Note 1
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic		P	P	P					See Below	Note 1
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: B/M, B/PWD, M/CD, B/CD/PWD, Note 1: Mflow, B/Bflow, Power flow).

Applications: Intra-operative- (liver, pancreas, gall bladder..)

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093488